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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,646

10/12/2004

Claude Mabilat

120162

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7590

02/13/2007

OLIFF & BERRIDGE, PLC

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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,646

Applicant(s)

MABILAT ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4 and 9 (in part), drawn to methods for determining an original animal species using a reagent specific for a nucleic acid selected from SEQ ID NO: 1-232 and 242-261.

Group II, claims 3, and 5-8 (in part), drawn to nucleic acids selected from the group consisting of SEQ ID NO: 1-232 and 242-261.

Group III, claims 10-14 (in part), drawn to nucleic acids selected from the group consisting of SEQ ID NO: 262-271.

Group IV, claims 15-17 (in part), drawn to methods for determining a group of original animal species using a reagent specific for a nucleic acids selected from the group consisting of SEQ ID NO: 262-271.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the linking technical feature of a method for determining an original animal species by obtaining a

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nucleic acid and contacting the nucleic acid with a probe complementary to a target sequence was known in the art at the time the invention was made. In particular, this methodology is disclosed by Matsunaga (Meat Science. 1999. 51: 143-148; cited in the IDS) and Colgan (Food Research International. 2001. 34(5): 409-414; cited in the IDS). Additionally, the claims are joined by the technical feature of a nucleic acid having at least 70% identity with SEQ ID NO: 1. However, nucleic acids having at least 70% identity with SEQ ID NO: 1 were known in the art at the time the invention was made. For example, Konno et al (NCBI Database, GenBank Accession No. AV225541, 14 November 2001) discloses an isolated nucleic acid which shares 77% identity with present SEQ ID NO: 1 (see nucleotides 174-186 of Konno). Further Konno (NCBI Database, GenBank Accession No. AV223259, 14 November 2001) discloses an isolated nucleic acid which shares 80% identity with present SEQ ID NO: 262 (see nucleotides 3-14 of Konno).

3. Further restriction requirement applicable to inventions I and II:

The inventions of groups I and II have been presented in improper Markush format, as distinct products and distinct methods are improperly joined in the claims. Each of the nucleic acids of SEQ ID NO: 1-232 and 242-261 (inventions I and II) and each of the nucleic acids of SEQ ID NO: 236-239 and 262-271 (inventions III and IV) is structurally and functionally distinct from each other in that each nucleic acid consists of a different nucleotide sequence and encodes for a protein having a distinct biological activity. For example, a nucleic acid comprising SEQ ID NO: 1 is chemically, structurally, and functionally different from a nucleic acid comprising SEQ ID NO: 2. Given the

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differences in the structure, function and effect the nucleic acids of SEQ ID NO: 1-232, 242-261, 236-239 and 262-271, these compounds are not considered to share a special technical feature as would be necessary to fulfill the requirement for unity of invention. These distinct compounds do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature." As the products and methods encompassed by the claims do not share a special technical feature, the distinct products and methods may not properly be presented in the alternative.

In response to this restriction requirement, Applicant is required to elect one or a particular combination of nucleic acids selected from the group consisting of SEQ ID NO: 1-232, 242-261 with respect to invention I and II, or SEQ ID NO: 236-239 and 262-271 with respect to invention III and IV.

This is a **restriction requirement** and should not be construed as an election of species.

4. Further restriction requirement applicable to invention II:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- I. CAA bases at positions 14689-14690-14691 of SEQ ID No. 235;
- II. CT bases at positions 15076-15077 of SEQ ID No. 236;
- III. CT bases at positions 15101-15102 of SEQ ID No. 237;

IV. GC bases at positions 14886-14887 of SEQ ID No. 238

V. ATA bases at positions 14713-14726 of SEQ ID No. 239

VI. T base at position 14641 of SEQ ID No. 262;

VII. A base at position 14778 of SEQ ID No. 263;

VIII. C base at position 15043 of SEQ ID No. 264;

IX. C base at position 15076 of SEQ ID No. 265;

X. C base at position 15101 of SEQ ID No. 266;

XI. A base at position 15109 of SEQ ID No. 267;

XII. C base at position 15115 of SEQ ID No. 268;

XIII. C base at position 15239 of SEQ ID No. 269;

XIV. T base at position 14519 of SEQ ID No. 270; and

XV. T base at position 14717 of SEQ ID No. 271.

Applicant is required, in reply to this action, to elect a single species or a particular combination of species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 12 encompasses species I-V

Claim 13 encompasses species VI-XV.

The following claim(s) are generic: Claims 10, 11 and 14.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The claims encompass mutations that are patentably distinct from one another with respect to their structure and effect. For example, the mutation of a C to T at position 1006 is chemically, structurally, and functionally different from the mutation of a G to A at position 1106. The mutations are not considered to share a special technical feature as would be necessary to fulfill the requirement for unity of invention. These distinct compounds do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature." As the products do not share a special technical feature, the distinct products and methods may not properly be presented in the alternative.

Applicants should note that if claims set forth in any of the remaining groups are amended so that they encompass specific mutations, these claims will also be subject to the same restriction requirement to elect a specific mutation or a specific combination of mutations.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
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CARLA J. MYERS
PRIMARY EXAMINER